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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,858	12/18/2001	Graham Stanley Leonard	P31220X2C2	1864

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/24/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,858	LEONARD ET AL.	
	Examin r	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2003 (paper no. 9)* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *08/817,911* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Application

Receipt of the Power to Inspect Notice filed 09/24/02, the request for extension of time (3 months) and the Amendment, both filed 03/26/03 is acknowledged.

Claims 25-26 are pending. Claims 9-24 have been cancelled by virtue of the amendment. Claims 25-26 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the

predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The nature of the invention is directed to a method of treating one or more well-known diseases, selected from alcoholism, anxiety, depression, Obsessive Compulsive Disorder, panic disorder, chronic pain, obesity, senile dementia, migraine, bulimia, anorexia, social phobia, pre-menstrual syndrome (PMS), adolescent depression, trichotillomania, dysthmia and substance abuse, which routinely occurs in the population.

(2) The state of the prior art

There are currently prior art teachings that provide medicaments directed towards patient comfort for treating such diseases.

(3) The relative skill of those in the art

The relative skill of those in the art is high. Research into the treatment of the instantly claimed diseases is at a bachelor's level and beyond. Secondary training is required for those scientists that do research in this field. It is not uncommon for scientists to have the level of Ph.D. of education.

(4) The predictability or unpredictability of the art

The unpredictability of the drug dosage art is fairly high. Effective dosages of paroxetine depend on the severity of the disease (i.e., senile dementia, bulimia, migraine, anorexia, etc), the condition of the patient and the frequency and route of administration.

(5) The breadth of the claims

The claims are very broad. The claims permit any oral paroxetine formulations that comprise enteric coatings. WIPO 92/09281 describes formulations comprising paroxetine that are both slow release and enterically coated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (WO 92/09281).

Johnson disclose an oral administration pharmaceutical composition for use in the treatment of bulimia and anorexia, comprising an effective amount of a selective serotonin reuptake inhibitor (SSRI) – paroxetine or a pharmaceutically acceptable salt thereof, wherein the preparation can be designated in the form of slow release and enteric coated tablets (see reference page 1, lines 17-36 through page 3, lines 1-25) and (claims 16,18 and 19). Examples of pharmaceutically acceptable salts of paroxetine are paroxetine hydrochloride, paroxetine hydrobromide, paroxetine acetate and paroxetine maleate. Johnson teach that the paroxetine preparation may be formulated for administration by any route, such as the oral route and can be in the form

of tablets, capsules, lozenges, etc. (page 2, lines 29-32). The tablets may be coated (i.e., enteric coated tablets) according to methods well known in the pharmaceutical practice and may, if desired, be designed to give slow release of paroxetine (page 2, lines 23 through page 3, line25).

Response to Arguments

Applicant's arguments filed 03/26/03 have been fully considered but they are not persuasive.

The applicant argued regarding the 35 U.S.C. 102(b) and 103(a) rejection claims stating, "The broad general descriptions of formulations in Johnson fails to anticipate the specific formulations of the present invention. The claims as amended, are now directed to both delayed and controlled release formulations. Nothing in Johnson teaches or suggests combining delayed release and controlled release technologies in a single formulation containing paroxetine. As such, nothing in Johnson anticipates or renders obvious the currently pending claims. Moreover, Johnson does not teach or disclose the nausea and vomiting associated with paroxetine administration. Johnson discloses that paroxetine may be used to treat bulimia and anorexia."

These arguments have been fully considered, but were not found to be persuasive. Johnson discloses an oral composition comprising paroxetine for the treatment of bulimia and anorexia. Johnson, at page 2, line 27 and page 3, lines 20-25 explicitly teach slow release (controlled release) and enteric (delayed release) coatings

for tablets. There is no significant distinction observed between the instant invention and the prior art since the prior art teaches an oral dosage formulation comprising an active ingredient, paroxetine for the treatment of anorexia and bulimia and also teaches various release forms, such as enteric coated tablets and slow release dosage forms, which are functionally equivalent to delayed and controlled release forms, respectively. Thus, the teachings of Johnson clearly meet the instant invention. Furthermore, there are no unexpected results that accrue from the use of applicant's instant release forms. Johnson teaches the generic concept of formulating both slow and enteric release dosage forms comprising paroxetine as the active ingredient. Therefore the instant invention is rendered unpatentable over the prior art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns
June 20, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600